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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,663	07/10/2002	Armin Prasch	03671/000K437-US0	6944

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
03/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,663	PRASCH ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-25,29-31 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-25,29-31 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' terminal disclaimer, filed on 19 December 2008.
- The 35 USC 112, 1st paragraph rejections of the previous Office action are withdrawn in view of the amendment.
- The obviousness-type double patenting rejection is withdrawn in view of the terminal disclaimer.

* * * * *

Terminal Disclaimer

The terminal disclaimer filed on 19 December 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,596,318 has been reviewed and is accepted. The terminal disclaimer has been recorded.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-25, 29-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heath, et. al. (WO 97/44015) in view of Marx, et. al. (WO 99/15637).

Heath, et. al. teach a granulated fibrin tissue adhesive formulation (*see* col. 3, lines 28-39). The disclosed formulation is comprised of:

- the blood plasma protein of instant claim 18 (*see* page 2, line 35);
- the thrombin of instant claim 18 (*see* page 2, line 35);
- the carrier granules of instant claim 18 (*see* page 3, lines 9-18);
- the active agent of instant claim 18 (*see* page 2, line 35);
- the carrier system of instant claims 19-21 (*see* page 3, lines 9-18);
- the granule comprised of an internal core of mannitol and external layer plasma protein of instant claims 22 and 23 (*see* page 3, lines 32-36);
- the substance which promotes wound healing of instant claim 28 (*see* page 2, line 35);
- the topical, parenteral, and transdermal routes of administration of instant claims 29-31 (see Example);
- the particle size (up to 50 μm in diameter) of instant claim 18 (*see* page 3, line14); and
- the process of producing a depot medicament of instant claim 34 (*see* page 3, lines 19-25).

While Heath, et. al. teach that a drug may be included with the disclosed formulation (*see* page 6, lines 3-8), the reference does not disclose the particular active ingredients listed in amended claim 18. However, use of said ingredients, *e.g.* antibiotics, in a biodegradable medicament formulation comprising a carrier system comprising a biodegradable blood plasma protein, was known in the art at the time the

instant application was filed, as evinced by Marx (*see*, *e.g.*, page 9, line 29 – page 10, line 16).

Heath, et. al. explain that a granulated blood plasma protein medicament formulation formed by spray-drying is beneficial because it provides, "…good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, not in the delivery system." *See* page 3, lines 1-7.

Although the Heath, et. al. reference does not disclose the fluidized bed drying step of instant claim 18, the process of fluidized bed drying recited in claim 18 is not essential to a determination of patentability of the formulation disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a granulated blood plasma protein medicament formulation, as taught by Heath, et. al in view of Marx et. al.. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a formulation because of good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, as explained by Heath, et. al.

* * * * *

Response to Arguments

Applicants' arguments filed on 26 August 2008 regarding the rejection under 35 USC 103 have been fully considered but they are not persuasive.

Applicants argue that the process step of claim 1 constitutes a limitation of the product claim because of materially different physico-chemical properties between the instant formulation and the prior art formulation, citing the 132 Declaration, filed on 5 April 2007. *See* remarks, pages 6-7.

Examiner reiterates that claim 18 is a product-by-process claim, not a process claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). *See* MPEP 2113.

Further, it is noted that while references WO-A-9218164, WO-A-9609814, and WO-A-9618388 mention the formation of hollow spheres, no mention of hollow spheres is made by Heath et. al. In fact, Heath et. al. suggest the procedures disclosed in the WO references optional, not required (*see* page 3, line 10). It is noted that Heath, et. al. are not using their microparticles for imaging purposes, as are the referenced WO documents. Rather, Heath et. al. use their microparticles for wound therapy and

surgical repair (*see* page 3, lines 3-4). Heath et. al. describe their microparticles as free-flowing, discrete, and substantially anhydrous (see page 5, lines 8-9), all characteristics of particles that are not hollow.

Assuming, *arguendo*, that only hollow spheres are produced by Heath et. al., applicants do not contraindicate the use of hollow particles in the specification; nor do they provide any criticality of using solid, as opposed to hollow particles.

* * * * *

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615